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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,407	08/01/2003	Douglas W. Losordo	58098 (71417)	6007

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,407	LOSORDO ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-74 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-48 and 66-74, drawn to methods of modulating endothelial cell proliferation in a mammal or reducing the severity of blood vessel damage in a mammal, comprising administering an ezrin modulating agent, pharmaceutical product comprising cells and kits for introduction of cells, classified in class 514, subclass 2, and for example.

II. Claims 49-61, drawn to a method for identifying a compound that modulates ezrin activity in vitro, classified in class 435, subclass 8, for example.

III. Claims 62-65, drawn to method of detecting binding between ezrin and mammalian cyclin A gene, classified in class 435, subclass 6.

Inventions I, II and III are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods are patently distinct, each having different starting materials, method steps and goals.

Because these inventions have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Further Restriction Within Groups I-III

For whatever group is elected, further restriction within the elected group is required, as follows:

If Group I is elected, a specific agent to be administered selected from the group of nucleic acid encoding the ezrin protein, antisense nucleic acid, TNF soluble receptor, anti-TNFα antibody, Y27632, TNFα, Rho kinase and cells.

The nucleic acid encoding ezrin protein, antisense nucleic acid, TNF soluble receptor, anti-TNFα antibody, Y27632, TNFα, Rho kinase and cells are patentably distinct for the following reasons: the polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules, and the nucleic acid encoding the ezrin protein and the antisense nucleic acid do not encode the polypeptides of TNF soluble receptor, anti-TNFα antibody, TNFα, Rho kinase. Therefore, methods of using the different compounds are patently distinct.

Administration of nucleic acid encoding the ezrin protein and administration of the antisense nucleic acid would have different effects, because they have different structures. For example, the DNA encoding the protein would have a different structure than the antisense nucleic acid, and also different function, either encoding the polypeptide of inhibiting expression of the polypeptide. DNA encoding protein is classified as class 536, subclass 23.5, and antisense is class 536 subclass 24.5. Therefore, methods of using them is patently distinct.

The TNF soluble receptor, anti-TNFα antibody, TNFα, Rho kinase, although they are all polypeptides, have different amino acid sequences, structures and activities. Although classifications for the TNF soluble receptor and the Rho kinase protein are overlapping, for

instance 530/350, each represents a patentably distinct product, and therefore methods of using them are patently distinct. The anti-TNF α antibody and TNFα are classified as 530/388.23, for example, and 530/351, and have different classifications from each other and the TNF soluble receptor and the Rho kinase, and therefore methods of using them are patently distinct.
The Y27632 is different from the other agents, in that it is a small organic molecule, classified in 544/60, for example, and has a different structure and activity from the other agents, and therefore method of using it is patently distinct.
The cells are living units comprised of thousands of different molecules and different structures, and are also classified in a different class and subclass from any other the other agents, 424/93.7, and methods of treatment with them are therefore patently distinct.
Additionally, use of each of the agents would require separate sequence searches, which would be a burden, and would not be used to determine the patentability of the use of any of the other agent.

Applicants are advised that this is not a species election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and/or different search requirements, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election for Group I

If Group I is elected, further species elections are required.

This application contains claims directed to the following patentably distinct species of the claimed invention: administration of an additional agent selected from aFGF, bFGF, VEGF-1, EGF, TGF-α, TGF-β, PD-ECGF, PDGF, TNFα, HGF, IGF, erythropoietin, CSF, M-CSF, Ang1, NOS, GM-CSF, VEGF, SLF, SDF-1, G-CSF, Ang2, FLT-3 ligand, VEGF-B, VEGF-C, VEGF-2 or VEGF-3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-26, 30-48 and 69-74 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Further species election. This application contains claims directed to the following patentably distinct species of the claimed invention: ischemia associated with infections, trauma, graft rejection, cerebrovascular ischemia, renal ischemia, pulmonary ischemia, limb ischemia, ischemic cardiomyopathy or myocardial ischemia.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-38, 40-48 and 69-74 are generic.

Species Election for Group II

If Group II is elected, further species elections are required.

This application contains claims directed to the following patentably distinct species of the claimed invention: means of detecting comprising measuring proliferation of the cells, cycling of the cells, measuring fluorescent reporter protein, measuring phosphorescent reporter protein, measuring luciferase reporter protein, measuring beta-galactosidase reporter protein and measuring phosphorylation of ezrin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 49 and 51-54 are generic.

Species Election for Group III

If Group III is elected, further species elections are required.

This application contains claims directed to the following patentably distinct species of the claimed invention: visualization by means of fluorescence, colorimetric, phosphorescence detection device or electrophoretic manipulation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 62 and 63 are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

EILEEN B. O'HARA
PATENT EXAMINER